

Remarks

This Amendment is responsive to the Final Office Action dated **March 8, 2011**.

Applicant has amended claim 25. No new matter has been added. Claims 1-24 were previously canceled. Claims 25-40 remain pending.

Applicant respectfully requests that the Amendment be entered as it is believed to place the application in condition for allowance or better form for appeal.

Claim Rejection—35 U.S.C. § 102

The Office rejection claims 25, 28-31, 34, and 37-39 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2005/0171563 to Heinrich et al. (“Heinrich”). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims.

In the Response to Arguments section of the current Office Action, the Office stated the following:¹

If one were to argue that the device of Shippert is not 'self-expanding' because it requires the absorption of fluid in order to expand, one could just as easily argue that Applicant device is not 'self-expanding' as it requires removal of a retention member in order for the device to expand. Thus, in arguing that the Shippert reference is not self-expanding, it would also imply the Applicant's device is also not truly 'self-expanding.' It is the Examiner's position that 'self-expanding' refers to the ability of a device to take on a different (i.e. self-expanded) state without additional user interaction - but only after that device has first been positioned/prepared by a user.

Applicant disagrees for several reasons.

First, the assertion that “Applicant’s device is also not truly ‘self-expanding’” because “it requires removal of a retention member in order for the device to expand”² is incorrect. The Office has confused Applicant’s *device* of claim 25 (“a medical device for delivering a therapeutic agent to an internal portion of a patient’s body”) with the self-expanding *delivery member* which forms a part of Applicant’s device. In claim 25, it is the *delivery member* which is self-expanding,

¹ Final Office Action, dated March 8, 2011, pages 5-6.

not the device.

Second, the source of the definition of “self-expanding” provided in the Office Action is unclear to Applicant. As stated in the Decision on Appeal³ in the instant case:

In the absence of an express definition of a claim term in the specification or a clear disclaimer of scope, the claim term is interpreted as taking any ordinary and customary meaning recognized by one of ordinary skill in the art consistent with the overall disclosure of the specification. *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007); *In re Morris*, 111 F.3d 1048, 1054 (Fed. Cir. 1997).

The Office has not cited any source or prior art reference to indicate that the definition of “self-expanding” provided in the Office Action is an ordinary and customary meaning recognized by one of ordinary skill in the art consistent with the overall disclosure of the specification, as required for interpretation.

Third, the Office is incorrect in asserting that “one could just as easily argue that Applicant device is not ‘self-expanding’ as it requires removal of a retention member in order for the device to expand.”⁴ The removal of the retention member of the device of claim 25 is not necessary in order to expand the delivery member, as asserted by the Office. Rather, the retention member is required to maintain the delivery member in its collapsed condition because of the delivery member’s self-expanding characteristics.

In the Response to Arguments section of the current Office Action, the Office stated the following:⁵

As to Applicant's arguments that 'water, saline, sterile water and the like' are not therapeutic agents, Examiner maintains that the use of these fluids aids in the performing of Heinrich's medical (i.e. therapeutic) procedure, and as such act as therapeutic agents.

Applicant respectfully submits that the Office has mischaracterized Applicant's argument. In no manner did Applicant argue that water, saline, sterile water and the like are not therapeutic agents. Rather, Applicant argued that the separate recitation in claims 25 of a self-expanding

² *Id.*

³ Decision on Appeal, dated August 26, 2010, page 3.

⁴ Final Office Action, dated March 8, 2011, pages 5-6.

delivery member and a therapeutic agent makes clear that the therapeutic agent does not expand the self-expanding delivery member. As such, it is improper for the fluid or liquid used to expand anchor 114 in Heinrich *to also be considered a therapeutic agent* for delivery to an internal portion of a patient's body.

Nevertheless, solely for the purposes of advancing prosecution, Applicant has amended claim 25. In particular, Applicant has amended claim 25 to further recite "wherein the delivery member expands from a collapsed state to a pre-determined diameter upon retraction of the retention member, and wherein the delivery member *expands without absorption of a liquid.*" Support for the amendment may be found throughout Applicant's specification, including, for example, at paragraph [0020], which states the following:

During operation of medical device 10, retention member 34 may be controlled by a user from proximal end 10a to maintain agent delivery member 18 in a collapsed condition (shown in FIG. 2) as agent delivery member 18 is positioned within a target treatment lumen. Thereafter, retention member 34 may be operated to release agent delivery member 18 from its collapsed condition, causing agent delivery member 18 to self-expand to a pre-determined diameter and bringing agent delivery member 18 into intimate contact with a target vessel wall 46.

In contrast to amended claim 25, Heinrich fails to disclose a delivery member that expands from a collapsed state to a pre-determined diameter upon retraction of the retention member and that *expands without absorption of a liquid.* Rather, Heinrich explicitly states,⁶ "[i]n use, anchor 114 expands from the initial condition to the expanded condition upon addition of moisture, fluid or liquid (e.g., water, saline, sterile water and the like) thereto."

For at least the reasons presented above and in Applicant's previous Amendment,⁷ the arguments in that Amendment being incorporated by reference in their entirety, Heinrich fails to disclose or suggest all the elements of amended independent claim 25. Applicant requests that the rejection be withdrawn and that claim 25 be allowed.

Claims 28-31, 34, and 37-39 depend from independent claim 25. At least by virtue of their dependency, claims 28-31, 34, and 37-39 are also patentable over Heinrich.

⁵ *Id.* at page 5.

⁶ Heinrich at paragraph [0059].

Claim Rejections—35 U.S.C. § 103

The Office rejected claims 25-35 and 37-40 under 35 U.S.C. § 103(a) as being unpatentable over Shippert as modified by Tanaka. The Office also rejected claims 26, 27, and 40 under 35 U.S.C. § 103(a) as being unpatentable over Heinrich as modified by Shippert. The Office also rejected claim 36 under 35 U.S.C. § 103(a) as being unpatentable over Heinrich.

Applicant respectfully traverses these rejections to the extent such rejections are considered applicable to the amended claims. Even if considered in combination, the applied references fail to disclose or suggest each and every feature of Applicant's claims, and would have provided no apparent reason for modification to include such features.

Claims 25-35 and 37-40

Even if considered in combination, the applied references fail to disclose all the features of amended claim 25. For at least the reasons presented above, Shippert fails to disclose a medical device for delivering a therapeutic agent to an internal portion of a patient's body that comprises, among other things, a self-expanding delivery member in operative communication with a shaft, wherein the delivery member expands from a collapsed state to a pre-determined diameter upon retraction of the retention member, and wherein the delivery member expands without absorption of a liquid, as recited in amended claim 25. As argued previously, the packing member in Shippert expands when it absorbs fluids.⁸ As such, Shippert fails to disclose a delivery member that expands from a collapsed state to a pre-determined diameter upon retraction of the retention member and that ***expands without absorption of a liquid***, as required by amended claim 25.

For at least the reasons presented above, the Office has failed to establish a prima facie case for non-patentability of Applicant's claim 25 under 35 U.S.C. § 103(a). Claims 26-35 and 37-40 depend from claim 25 and, at least by virtue of their dependency, are also non-obvious over the applied references. Withdrawal of this rejection is requested.

Claims 26, 27, and 40

As indicated above, Heinrich fails to disclose or suggest all the features of amended

⁷ Amendment, dated January 26, 2011.

⁸ See, e.g., Shippert, col. 5, lines 7-25.

independent claim 25 from which claims 26, 27, and 40 depend. As such, the addition of any disclosure in Shippert with respect to the particular features of claims 26, 27, and 40 doe nothing to remedy the deficiencies of Heinrich. Thus, claims 26, 27, and 40 are non-obvious over the purported combination of Heinrich and Shippert. For at least these reasons, the Office has failed to establish a *prima facie* case for non-patentability of Applicant's claims 26, 27, and 40 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

Claim 36

As indicated above, Heinrich fails to disclose or suggest all the features of amended independent claim 25 from which claim 36 depends. Regardless of what the Office alleged to be a matter of design choice, or what a person of ordinary skill allegedly would have known, with respect to the elements of claim 36, Heinrich still fails to disclose or suggest all the features of independent claim 25.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Applicant has discussed several specific claims above, but does not acquiesce to any of the Examiner's rejections or prior art interpretations. Accordingly, Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicants hereby petition for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

Respectfully submitted,

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